K033039

McKinley, Inc.
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OCT - 7 2003

McKinley

510(k) Summary—Special 510(k) for Modifications to the McKinley Accufuser, Accufuser Plus & Standard Procedure Kit

Date Prepared:	26 September 2003
Submitter:	McKinley, Inc. 4080 Youngfield Street Wheat Ridge, CO 80033 Phone: 303-420-9569 Fax: 303-420-8585 Contact for questions: Andy Lamborne
Trade Name:	Accufuser; Accufuser Plus; Standard Procedure Kit
Common Name:	Elastomeric Infusion Pump Kit
Classification Name:	Elastomeric Infusion Pump
Classification Panel:	General Hospital and Personal Use Device
Regulation Number:	Class II, 880.5725
Panel:	80
Procode:	MEB – Elastomeric Infusion Pump
Original cleared 510(k):	K023098
Establishment Registration:	1723533
Owner/Operator Number:	9027257

5. Summary of Safety and Effectiveness of the Accufuser System

5.1 This submission is intended to notify the Food and Drug Administration that McKinley, Inc. intends to market a modification to an existing device (K023098) called the Accufuser/Accufuser Plus system. The modification to the existing device is the addition of procedure kits containing different accessories.

5.2 The cleared indications for use for the Accufuser/Accufuser Plus system are as follows:

The Accufuser and Accufuser Plus systems are intended for general infusion use. Routes of infusion include intravenous, percutaneous, subcutaneous, intra-arterial and epidural, and into the intra-operative (soft tissue/body cavity) site. The Accufuser Plus is also intended for patient-controlled infusion using the integrated bolus button. General infusion uses include pain management for preoperative, perioperative, and postoperative surgery.

The Accufuser and Accufuser Plus systems are also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous.

The Accufuser/Accufuser Plus system is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

5.3 Summary of the Modification

5.3.1 Standard Procedure Kits will have an optional multi-port catheter with a longer fenestrated length for wetting a larger area. The current kits have a standard epidural catheter with a small number of fenestrations over a short length.

5.3.2 Standard Procedure Kits will have an optional fixed-hub catheter. The current kits have catheters that utilize a Tuohy-Borst adapter or alligator clip-style adapter.

5.3.3 Standard Procedure Kits will have an optional break-away introducer needle, allowing use of a fixed-hub catheter. The current kits have a non-break-away introducer needle that requires use of a catheter with separate connector (i.e., Tuohy-Borst or alligator clip style adapter).

5.3.4 Standard Procedure Kits will have an optional fill port cover, inhibiting access to the fill port once the cover is attached.

5.4 Conclusion: The new optional accessories for the Standard Procedure Kit do not raise any new safety and efficacy concerns when compared to the original Accufuser device that is already legally marketed. The Accufuser, Accufuser Plus, and Standard Procedure Kit is substantially equivalent to the named predicate device (K023098).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 7 2003

Mr. Andrew N. Lamborne
Director of Engineering
McKinley Medical
4080 Youngfield Street
Wheat Ridge, Colorado 80033

Re: K033039
Trade/Device Name: Accufuser, Accufuser Plus, Standard Procedure Kits
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: MEB
Dated: September 26, 2003
Received: September 29, 2003

Dear Mr. Lamborne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

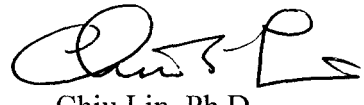
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Indications for Use Statement

Applicant: McKinley, Inc.

510(k) Number (if known): K033039

Device Name: Accufuser; Accufuser Plus, Standard Procedure Kits

Indications for Use:

The Accufuser and Accufuser Plus systems are intended for general infusion use. Routes of infusion include intravenous, percutaneous, subcutaneous, intra-arterial and epidural, and into the intra-operative (soft tissue/body cavity) site. The Accufuser Plus is also intended for patient-controlled infusion using the integrated bolus button. General infusion uses include pain management for preoperative, perioperative, and postoperative surgery.

The Accufuser and Accufuser Plus systems are also intended for continuous and/or intermittent delivery of medication (such as local anesthetics or narcotics) to surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural or percutaneous.

The Accufuser/Accufuser Plus system is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucuzzella

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033039

(Optional Format 3-10-98)